

Postmyocardial infarction education is effective but not enough on its own

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Giannopoulos *et al*¹ report that delivering a stand-alone educational programme following myocardial infarction (MI) reduces the risk of cardiovascular events. This single-centre trial, based in a university hospital in Athens, randomised 329 postmyocardial patients to either an 8-week programme of structured education plus usual care (intervention) or usual care (control). The authors reported that the intervention consisted of 10 hours of contact on risk factor management, lifestyle and drugs, delivered by a non-healthcare personnel with interactive patient sessions, aimed at enhancing patient adherence to lifestyle change and treatment compliance. At a mean follow-up of 17 months, the authors reported an HR for the primary composite outcome (all-cause death, MI, stroke and hospitalisation) of 0.48 (95% CI 0.32 to 0.73) and major adverse cardiovascular and cerebrovascular event of 0.49 (0.27 to 0.82). With similar mortality in both groups, improvements were driven by reduced rates non-fatal events in intervention compared with control: MI (13 vs 22), stroke (2 vs 7) and cardiovascular hospitalisation (14 vs 22).

What is the mechanistic basis of this improvement in non-fatal events? As noted by the authors, an improvement in risk factors is likely to be a key explanation. Greater changes from baseline at 12 months in the education group compared with controls were seen in low density lipoprotein cholesterol (median change: -53.5 vs -35.0 mg/dL), systolic blood pressure (-8.0 vs -2.0 mm Hg) and body mass index (0 vs 2.0 kg/m², $p < 0.001$). Intriguingly, no difference in adherence to medication (including use of statins and antihypertensives) over the duration of the study or between the two groups was seen, indicating that that risk factor improvement (and consequent reduction in the risk of events) was the result of changes in lifestyle behaviour following participation education intervention. As behavioural outcomes such

as diet and physical activity were not reported, that the mechanistic basis of the education intervention was improved lifestyle remain a hypothesis.

In contrast to the Giannopoulos trial, the meta-analysis of the Cochrane review of randomised controlled trials published in 2017 showed there to be no strong evidence that participation in educational interventions improved either all-cause mortality (relative risk (RR) 0.80, 95% CI 0.60 to 1.05) or cardiovascular events (fatal and/or non-fatal MI: RR 0.63, 0.26 to 1.48; coronary artery bypass graft and percutaneous coronary intervention: RR 0.58, 0.19 to 1.71; hospitalisations: RR 0.93, 0.71 to 1.21) for people with coronary heart disease². Although based on sizeable literature, that is, 22 trials in 76 864 participants, the Cochrane team identified several limitations in the included evidence base. The case mix of participants recruited to trials varied considerably: MI, postrevascularisation and stable angina with a wide range of disease severity and timings from diagnosis or event. There was substantial variation in the nature and dose of interventions employed by trials, ranging from one trial that employed a single 40 min face-to-face teaching session plus a 15 min follow-up phone call to a 4-week residential stay followed by 11 months of regular nurse-led follow-up sessions. Because of poor reporting of trials methods, there was considerable uncertainty in trial methodological quality. Given these limitations, the Cochrane authors called for: ‘... *further definitive research into education interventions for people with CHD...*’. Giannopoulos *et al* respond to this call with a trial that: (1) targets a defined homogenous population of MI patients, (2) provides a transparent report of study methods, including description of generation of the randomisation sequence, and (3) reports a primary outcome assessed by blinded event adjudication.

To fully understand the applicability of the Giannopoulos trial, it is important that we view its educational programme through the lens of a ‘complex intervention’, that is, as an intervention whose efficacy/effectiveness depends on number of interacting factors: the theoretical basis for the intervention, the context

and method of intervention delivery and how recipients respond to receipt of the intervention (eg, changes in health behaviour).³ Reporting frameworks have been developed for complex intervention trial authors to supplement the core Consolidated Standards of Reporting Trials requirements for randomised controlled trials.^{4,5} Additional reporting items include the intervention underlying theoretical basis (how will the intervention cause change?), method of intervention development (eg, were patients, clinicians and other key stakeholders involved in the intervention design?), fidelity of delivery (eg, what checks were in place in the trial to check that the intervention was delivered as planned?) and the costs and resources (eg, staffing) to deliver of the intervention. That such details were not available limits our ability to judge the applicability of this educational intervention to the UK National Health Service or other healthcare settings.

So, how should the Giannopoulos trial inform our clinical practice? While a positive study, the addition of the outcome findings of this trial does not overturn the ‘neutral’ meta-analysis findings of the Cochrane review above. It would therefore seem appropriate that we continue to follow the clinical practice conclusions of the Cochrane authors and recommend educational interventions as part of a wider comprehensive programme of rehabilitation that also includes exercise and psychological support, consistent with national guidance for the management of people with MI.^{6,7}

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